ST. JUDE MEDICAL
CARDIAC RHYTHM MANAGEMENT DIVISION

CONFIDENTIAL INVENTION DISCLOSURE TO PATENT COUNSEL

FOR PATENT GROUP USE ONLY:
DOCKET NUMBER: A00E1220
DATE RECEIVED:
RECEIVED BY: L. Neece

TO: Malcolm J. Romano, Chief Patent Counsel
FROM: Matt Whitlock
SUBJECT: Request for Legal Advise Regarding Patentability For:

TITLE OF INVENTION: Can in Can Packaging for Telemetry Shielding

For IRB purposes, please specify topic:

Leads (All leads, adapters, etc.)

X **Programmers** (including diagnostics, telemetry/communications, trans-telephonic, etc.)

X **Pacing** (including Brady/CHF/Multi-Site Stimulation, Auto functions, pacer-specific packaging, etc.)

X **ICD** (specifically, any tachyarrhythmia detection or therapy, ICD-specific packaging, etc.)

Other _____

FAST TRACK (In addition to the above, check this box only if the invention was conceived in a Strategic Innovation Brainstorming Session moderated by Jonathan Losk)

THIS FORM HAS CHANGED SO PLEASE READ EVERYTHING CAREFULLY.

NOTE: Please TYPE, EMAIL an electronic copy, and then submit a WITNESSED original (signed in BLUE INK) of this invention disclosure form as soon as you have made an invention. If you have any questions, consult the Patent Department and/or the "***Guidelines for Drafting Invention Disclosures*** (see http://ussyin01/patents/patent/disclo~1.doc).

1. **BACKGROUND OF THE INVENTION:** In the space below, briefly describe the purpose or problem your invention is trying to solve, including any background, rationale, or state-of-the-art information.

Long range telemetry (LRT) for implantable medical devices allows for communication with implanted medical devices at distances greater than conventional "wand" telemetry in use today. Our design calls for the pacer leads to be used as the antenna for transmitting and receiving the data signals. However, current pacemakers employ filters to block the radio frequencies needed for telemetry. The design described here overcomes this problem allowing the lead to be used as a pacing/sensing lead and as a radio frequency (RF) antenna without causing interference to the pacemaker functions.

2. **SUMMARY OF THE INVENTION:** In the space below, include a **brief, narrative, *functional* descripti n** of the nature and substance of the invention so as to provide an **overview** of what the invention accomplishes.

Isolation Technique with Dual Enclosure Shielding for Implantable Device Telemetry: The feedthrough from the pacemaker lead is split into two connections using a circuit known as a diplexer. The diplexer allows two signals of different frequencies to be transmitted along the same conductor. The filter leading to the pacing/sensing circuitry is tuned to pass the low frequencies of the ECG signal. High frequencies are blocked and therefore do not interfere with the sensing of the ECG. The other connection on the diplexer connects to the radio transceiver. This filter is tuned to the carrier frequency of the transceiver. Thus, low frequency signals such as the ECG are blocked.

The diplexer and filtering circuitry as well as the RF transceiver would be placed in a second metal case within the external titanium can. The interior can could be made from titanium like the exterior can or made from another conducting metal. A second feedthrough would provide a connection to the diplexer and transceiver circuit. The purpose of the interior can would be to isolate the RF components from the pacer circuitry. The metal shield would block spurious signals emanating from the diplexer or transceiver from interfering with the pacemaker sensing and pacing functions.

3. **DRAWINGS:** The importance of high quality drawings cannot be emphasized enough: not only does the preparation of the specification rely on good drawings, but more importantly, anything that is ultimately claimed must be shown in the drawings. Therefore, please attach additional sheets which will provide a complete set of drawings for your invention as contemplated at this time, preferably using "tiered" diagrams. Please indicate below the type and nature of the drawings that are attached along with the number of attachments: 1 page.

- ☐ an anatomically correct drawing of a heart with leads/electrodes properly identified for this particular invention
- ☐ a high level block diagram of a stimulation device (or programmer, etc.) identifying key blocks and/or novel features for this invention (must have appropriately labeled output terminals corresponding to the heart/lead/electrode diagram), adding additional blocks as needed for the particular invention
- X a detailed block diagram and/or a schematic of any novel circuits or new blocks identified in the high level block diagram.
- ☐ one or more flow charts describing any algorithm(s), using high level functional description rather than specific solutions
- ☐ mechanical drawings (e.g., leads, connector tops, packaging, etc.) should be fairly accurate representations. If electronic drawings are not available, you may take a prior art figure and modify it to illustrate the new features.
- ☐ other: _____

4. **PREFERRED EMBODIMENT:** Under this heading, describe or attach a clear and concise description of the invention, including the "**best mod** " for carrying out the invention as contemplated by the inventor(s) at the time of this writing.

The preferred embodiment would include both the diplexer and dual enclosure design to provide optimal isolation. The diplexer is designed to direct RF signals to the transceiver and the electrocardiograph signals to the sense/stimulate functions. The diplexer works in the reverse direction as

well: RF transmissions from the transceiver would conduct out to the pacer lead but not into the sense/stimulate functions. Similarly, the pacing stimuli would conduct out to the lead but would not affect the RF telemetry. The interior enclosure isolates the pacemaker circuitry from spurious RF signals that could interfere with pacemaker function. In conjunction with the diplexer, the pacemaker would be immune from RF interference while at the same time, capable of communicating via RF telemetry.

5. **ALTERNATE EMBODIMENTS:** Under this heading, describe or attach alternate ways for carrying out the invention, as presently known or contemplated by the inventor(s) at the time of this writing, using equivalent or similar techniques to achieve the same result. Include all embodiments that you are currently aware of that address the presently known needs and, if possible, those in the near future.

The diplexer filters can be constructed in several ways. The design described here is formed with inductors and capacitors but variations on the bandpass and bandstop filters are possible. Such variations could contain more complex filters that selectively pass and block the desired frequencies or bands of frequencies.

6. **DESIRED CLAIMS, FEATURES AND ADVANTAGES:** In **FUNCTIONAL LANGUAGE,** describe the **novel features** that you consider as key to the invention and/or the **advantages** achieved by this invention.

a) Implantable medical device (IMD) with a dual can structure and double feedthrough design.

b) IMD with a special housing to isolate RF components (transmitter and receiver, diplexer) from the pacing circuitry.

c) IMD with diplexer circuitry to allow pacing lead to be used as pacing/sensing lead and a radio frequency antenna.

d) _____

e) _____

f) _____

7. **CONCEPTION:**

Is the invention recorded elsewhere in engineering documentation:

1. The invention is described on pages: 26 of **Engineering Notebook No:** 2866
2. The invention is described in **Engineering Document No(s):** _____
3. **Successful test results,** if any, were recorded where: _____
4. The invention is currently in **X research,** **animal testing,** or **product development.**

8. **PLANNED USES** (if known):

(a) For database searching purpose, enter a simplified **"Product Feature Name"** (e.g., DAO, PreVAB, AutoSearch, Prediction Model, Lead surveillance, etc.) that is used to describe your invention:

Telem try / Long Range T lemetry

(b) This invention's **actual first use will b** (specify model name) or **X could be** used in a future product (specify a "family" name or engineering platform):

X **PACEMAKER:** All_____

X **DEFIBRILLATOR:** All_____

CONSOLIDATED PLATFORM:_____

PROGRAMMER: _____

LEADS: _____

OTHER: _____

9. **PUBLIC DISCLOSURES** (if known):

a) Has there been any other **PUBLIC USE, EXPERIMENTAL USE** or X **DISCLOSURE** to anyone outside of St. Jude Medical CRMD? **YES**

(i) Date and nature 9/27/00 Consultant meeting with Mark Simon, President of Wireless Systems Research _____

_____

b) **PUBLICATIONS**

1) Has a **manuscript** been accepted for publication at the time of the disclosure? **NO**

(i) Specify: **NASPE ACC AHA Cardiostim World Pacing Symposium Other**

_____

(ii) Attached is a copy of the Abstract

(iii) Expected publication date:_____

2) Are you aware of any **related patent applications** by CRMD describing this invention? **NO**

(i) Docket No(s). and/or Title(s) _____

_____

3) Are you aware of any **issued patents** that you consider relevant to invention? **YES**

(i) X Attached are copies of any relevant patents: Patent Number 5,058,581

c) **SALE/FULL MARKET RELEASE** (may be entered when available)

1) Has a Full Market Release for Europe (TUV) occurred (enter date):_N/A_____

2) Has a Full Market Release for the US (FDA) occurred (enter date):_N/A_____

d) **FIRST IMPLANT**

1) A first implant **anywhere in th world** has occurred is tentatively scheduled for: **NO**

(i) Date:_____

(ii) City, Country (when known):_____

(iii) Attach copies of actual pages describing this feature from the Physicians Manual, **OR**
Attach copies of the pertinent proposed description of this feature for the Physicians Manual, if available.

10. IDENTIFICATION OF CONTRIBUTOR(S): Please list ach person who has **CONTRIBUTED TO THE CONCEPTION** of th inv ntion.

1. Name **Matt Whitlock** Tel. Ext. 2240 Citizenship USA
   Residence 14955 Dickens St #202 Sherman Oaks LA CA 91403
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date Supervisor B. Shankar

2. Name **Mark Kroll** Tel. Ext. _____ Citizenship _____
   Residence 943 Smaloa, Simi Valley CA USA 93065
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date Supervisor Shankar

3. Name **Balakrishnan Shankar** Tel. Ext. 2193 Citizenship INDIAN
   Residence 26033 MORENO STREET, VALENCIA, LA, CA 91355
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date Supervisor MARK KROLL

4. Name _____ Tel. Ext. _____ Citizenship _____
   Residence _____
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date _____ Supervisor _____

5. Name _____ Tel. Ext. _____ Citizenship _____
   Residence _____
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date _____ Supervisor _____

6. Name _____ Tel. Ext. _____ Citizenship _____
   Residence _____
   Street City County State Zip
   Signature _____ (Sign in Blue Ink) Date _____ Supervisor _____

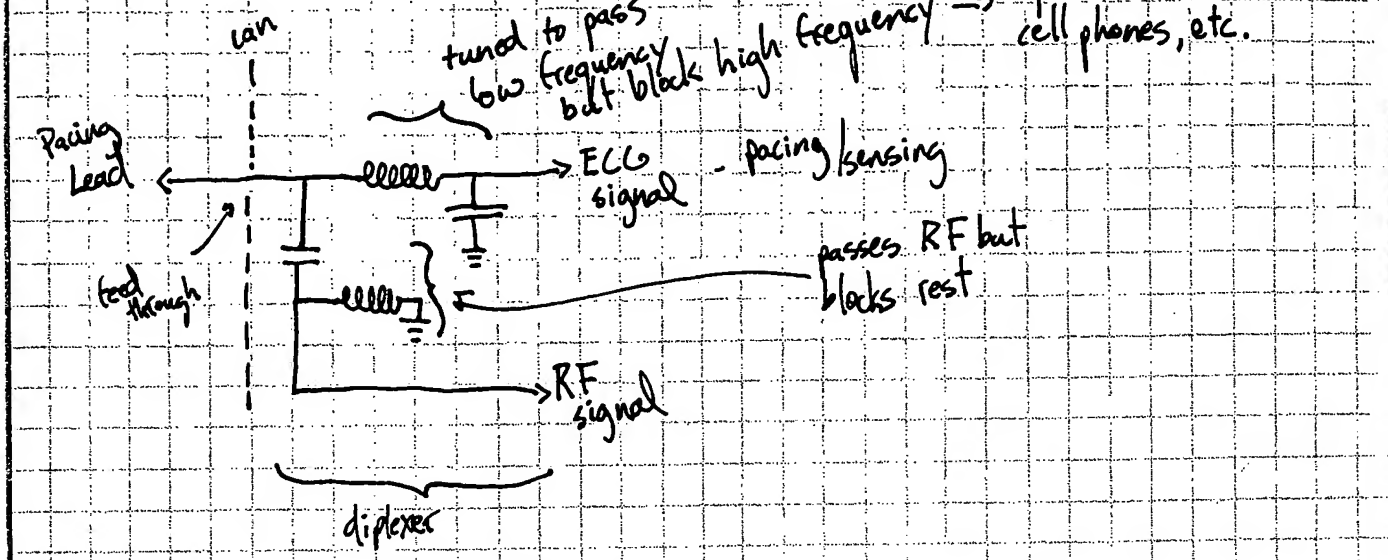
WITNESSES: I have **READ** and **UNDERSTOOD** the attached invention, and/or the invention has been explained to me.

Signature of Witness T. J. Cruz _____ (Sign in Blue Ink) Date__

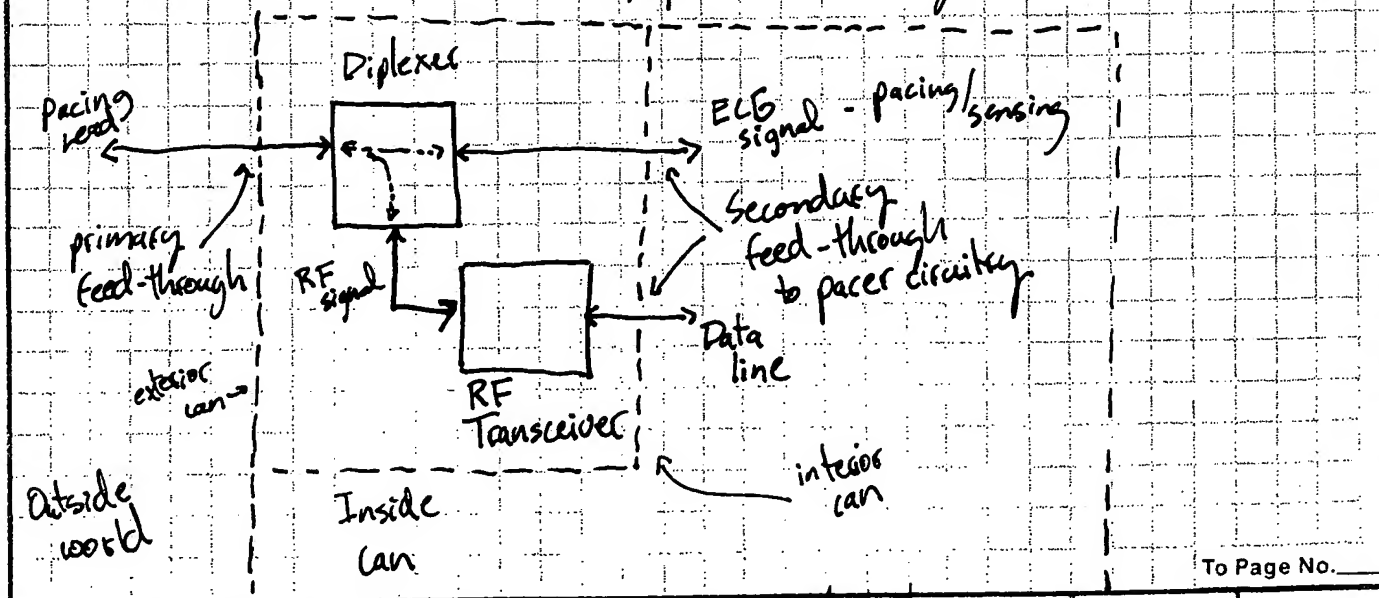
Signature of Witness C. Sorensen _____ (Sign in Blue Ink) Date__

From Page No.

- Diplexer Technique for use with LRT Communication with "Can in Can" shielding



- 2 Chamber Can Design - isolates RF components from rest of pacer circuitry



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Witnessed & Understood by me.	Date	Invented by	Date
T. J. Cox		R corded by	